

201-14402



NCIC HPV  
Sent by: Mary-Beth  
Weaver

04/15/2003 02:17 PM

To: NCIC HPV, moran.matthew@epa.gov  
cc:  
cc:  
Subject: Environmental Defense comments on Hexanedioic Acid, DI-C7-C9  
Branched and Linear Alkyl Ester (97 Adipate), CAS No. 68515-75-3



Richard\_Denison@environmentaldefense.org on 04/15/2003 10:06:44 AM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen  
Roswell/DC/USEPA/US@EPA, frjoha@solutia.com  
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Hexanedioic Acid, DI-C7-C9 Branched and Linear Alkyl Ester (97  
Adipate), CAS No. 68515-75-3

(Submitted via Internet 4/15/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov,  
boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and  
frjoha@solutia.com)

Environmental Defense appreciates this opportunity to submit comments on  
the robust summary/test plan for Hexanedioic Acid, DI-C7-C9 Branched and  
Linear Alkyl Ester (97 Adipate), CAS No. 68515-75-3.

The test plan for 97 Adipate was prepared by Solutia, Inc. 97 Adipate is a  
UVCB Chemical (i.e., a Chemical Substance of Unknown or Variable  
Composition, Complex Reaction Products and Biological Materials, as defined  
in the TSCA Chemical Substance Inventory), so it is of unknown or variable  
composition and the sponsor has declined to provide any chemical structure  
or chemical composition data. Nevertheless, the sponsor proposes to use  
data from other chemicals as surrogates to fulfill the requirements of the  
HPV program, and are in essence proposing a category. Because neither the  
structure nor the composition of the HPV chemical are provided, however, we  
cannot concur that the use of data from surrogate chemicals is justified.  
Accordingly, we do not agree with the sponsor's claims that no additional  
studies are needed.

97 Adipate has a broad array of uses including applications as a  
plasticizer, especially in cases where low-temperature flexibility is  
needed. These applications include rainwear and food packaging, so there is  
clearly the opportunity for consumer as well as worker exposure. Moreover,  
opportunity for environmental contamination also exists.

Specific comments on the test plan are as follows:

1. Although the composition of 97 Adipate is variable, the sponsor should  
have information on representative samples and the range of concentrations  
for various constituents. This information should be provided in the test  
plan. Without such data, the plan is incomplete and we cannot fully  
evaluate its adherence to HPV requirements.
2. The sponsor proposes to use data from surrogate chemicals to fulfill the  
requirement for chromosomal aberration data. For the reasons specified in  
our general comments, we do not agree and we recommend that chromosomal  
aberration studies be conducted directly on 97 Adipate.
3. The sponsor states that although 97 Adipate possesses a high  
bioaccumulation factor, the sponsor argues that this is not of concern  
because the chemical is degraded in biological systems and in the  
environment. While we do not accept this reasoning (bioaccumulation and

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biodegradation being separate issues), if degradation does occur, then the degradation products should be tested for ecological toxicity. It is likely that they will have much higher water solubility than the parent compound, so testing of the degradation products should circumvent the problem of the limited solubility of 97 Adipate.

4. The robust summaries for the repeat dose and developmental toxicity studies state that the test substance used was "other TS" and that it was 99% pure. What is "other TS" and how can purity be determined on a substance of unknown and variable composition? Until data on the composition of the test substance are made available, we reserve judgment on whether the repeat dose and developmental toxicity studies are adequate to fulfill HPV requirements.

Thank you for this opportunity to comment.

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